K071041

MAY 1 1 2007

510(k) Summary – CoaguChek XS Plus System

Introduction

According to the requirements of 21 CFR 807.92, the following information provides sufficient detail to understand the basis for a determination of substantial equivalence

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Submitter name, address, contact

Roche Diagnostics
9115 Hague Rd
Indianapolis IN 46250
(317) 521-3723

Contact person: Theresa A. Bush

Date prepared: April 11, 2007

Device Name

Proprietary name: CoaguChek® XS Plus System

Common name: Prothrombin time test

Classification name: Prothrombin time test

Device Description

The CoaguChek XS Plus system is a portable coagulation monitoring system to monitor prothrombin time (PT) in patients receiving oral anticoagulant therapy. The system uses the amperometric detection of thrombin in the blood sample. A test strip is used to determine a PT value from 10 uL of whole blood. Onboard quality control is available on every test strip and the system also features an optional external quality control material (CoaguChek XS PT Control).

Intended use

Intended for use by professional healthcare providers for quantitative prothrombin time testing for the monitoring of warfarin therapy. The system uses fresh capillary or non-anticoagulated venous whole blood.

Predicate Device

The Roche Diagnostics CoaguChek XS Plus System is substantially equivalent to to the previously cleared CoaguChek XS System (K060978).

Similarities	The table below indicates the similarities between the CoaguChek XS Plus System and the CoaguChek XS System.

Feature/Claim	Modified Device: CoaguChek XS Plus	Predicate Device: CoaguChek XS
General features		
Intended Use	Intended for use by professional healthcare providers for quantitative prothrombin time testing for the monitoring of warfarin therapy. The system uses fresh capillary or non-anticoagulated venous whole blood.	Same
Fundamental Technology	Electrochemical technology with amperometric (electric current) detection of thrombin activity	Same
Sample Type	Capillary whole blood or non-anticoagulated venous whole blood	Same
Sample Volume	The blood drop must be a minimum of 10 µL	Same
Test Strip	CoaguChek XS PT Test Reference number: 04625315160	Same
Onboard control	Built into every test strip	Same
External quality control	CoaguChek XS PT Controls are available as optional external controls	Same
System Performance Characteristics		
Hematocrit Range	Hematocrit ranges between 25 – 55% do not significantly affect test results	Same
Bilirubin	Bilirubin up to 30 mg/dL have no significant effect on test results	Same
Triglyceride	Lipemic samples containing up to 500 mg/dL of triglycerides do not significantly effect on test results	Same
Hemolysis	Hemolysis up to 1000mg/dL have no significant effect on test results	Same
Heparin	Test results are unaffected by heparin concentrations up to 0.8 U/mL.	Same
Low Molecular Weight Heparin	The CoaguChek XS PT Test is insensitive to low molecular weight heparins (LMWH) up to 2 IU anti-factor Xa activity/mL	Same
Measuring Range	0.8 to 8.0 INR	Same

Modifications	The following table lists the modified features of the CoaguChek XS Plus System.

Feature/Claim	Modified Device: CoaguChek XS Plus System	Predicate Device: CoaguChek XS System
General features		
Strip lot identification	Handled automatically by meter using barcode reader and information on test strip code chip	Handled manually
Memory Capacity	•500 test results with date, time, patient ID, operator ID •60 code chip records	•100 test results with date and time •No code chip records maintained
Quality Control (QC) Lockout	If QC results fail, the operator is locked from performing a test.	Not available
Control Target values	Lot-specific target values provided on QC code chip	No QC code chip; lot -specific values found on value sheet
Hardware modifications and features		
Components	Three: • Handheld Basic Module (HBM) • Measurement Module (MM) • Barcode Reader (BR)	One: • Measurement Module (MM)
Handheld Basic Module (HBM)	An additional component which provides the power management of the AC-adapter or rechargeable batteries and houses all the data management features including • IR module for data transfer to external device • Beeper • Codekey connectors (for test strip and control) • On/off button	No HBM. Peripheral functions located directly on MM •IR module is on MM •Beeper is on MM •Codekey connector found on MM •on/off button on MM

Measurement Module (MM)	Converts raw signals from test strip into final PT result. • Same measurement software as XS, ensuring same test processes and result • Strip chamber cover with modified blue cover • Same printed circuit board with differences in assembled components for peripheral functions: •Additional connector to HBM •Beeper, codekey connectors, IR module and on/off buttons are on the HBM, not on the MM •Set and memory buttons are accessible via touch screen; not as separate keys	• Contains measurement software for generation of PT result from raw signal • Contains strip chamber cover • Houses peripheral functions such as beeper, code chip connector, IR-module, and three buttons (on/off, memory, setup)
Barcode Reader (BR)	Separate board with camera and electronics; enables automatic Strip Lot Identification by reading 2D barcode on test strip and comparing to codekey	No bar code reader
Software modifications and features		
Measurement oftware	IDENTICAL to measurement software on XS	Converts raw signal into PT result
Barcode reader software	Software communicates with barcode reader and responds to barcodes	No barcode reader
Code chip (aka codekey) software	• Codekey information stored in data manager; transferred to measurement manager • Codekey for liquid QC	General codekey handling in measurement module. No codekey for liquid QC.
Errorhandling	Handled in data manager with additional features	Handled in measurement module
Connection to Host	Infrared via POCT/ICI communication	Infrared via ICI communication

Infrared communication switch	Can switch between POCT and ICI	Not present
QC handling	QC measurement, results, lockouts handled in data manager	Not handled in software
Patient ID	Software allows for entry of a Patient ID	Not available
User ID	Software allows for the entry of a User (Operator) ID	Not available
Administrator ID	Software allows for the entry of an Administrator ID	Not available
User Interface	Text-enhanced icon-based user interface	Icon-based user interface
Language	12 languages can be selected	Not available
HBM software features	• Boot process and software updates • Driver for communication between internal components • Power management • Display software • Driver for clock and interrupt • Watchdog for configuration, powermodes	No HBM
System Performance Characteristics		
Accuracy compared to lab reference	Venous Blood: N = 811 Slope = 1.090 Intercept = -0.2 Correlation = 0.974 Capillary Blood: N = 822 Slope = 1.075 Intercept = -0.1 Correlation = 0.972	Venous Blood: N = 710 Slope = 1.034 Intercept = -0.02 Correlation = 0.974 Capillary Blood: N = 700 Slope = 1.006 Intercept = 0.032 Correlation = 0.971
Whole Blood Precision	Venous Blood: N = 399 Mean INR = 2.32 SD = 0.046 CV = 2.00	Venous Blood: N = 357 Mean INR = 2.59 SD = 0.06 CV = 2.42

	Capillary Blood: N = 399 Mean INR = 2.26 SD = 0.077 CV = 3.39	Capillary Blood: N = 344 Mean INR = 2.59 SD = 0.11 CV = 4.35
Control Precision	Level 1 N = 538 Mean INR = 1.18 SD = 0.04 CV = 3.37 Level 2 N = 535 Mean INR = 2.95 SD = 0.12 CV = 4.10	Level 1 N = 54 Mean INR = 1.20 SD = 0.01 CV = 1.1 Level 2 N = 54 Mean INR = 2.49 SD = 0.06 CV = 2.3

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

MAY 11 2007

Roche Diagnostics
C/O Theresa A. Bush, PhD, RAC
9115 Hague Road
Indianapolis, Indiana 46250

Re: k071041
Trade/Device Name: CoaguChek® XS Plus System
Regulation Number: 21 CFR 864.7750
Regulation Name: Prothrombin time test
Regulatory Class: Class II
Product Code: GJS
Dated: April 11, 2007
Received: April 12, 2007

Dear Dr. Bush:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

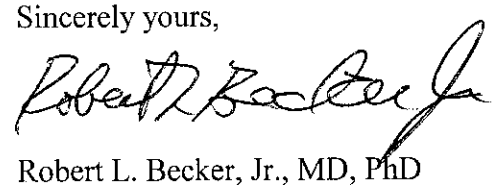
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed

predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (301) 594-3084. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150, or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,



Robert L. Becker, Jr., MD, PhD
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Division of Immunology and Hematology
Office of *In Vitro* Diagnostic Device Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K071041

Device Name: **CoaguChek XS Plus System**

Indications For Use:

The CoaguChek XS Plus System is intended for use by professional healthcare providers for quantitative prothrombin time testing for the monitoring of warfarin therapy. The system uses fresh capillary or non-anticoagulated venous whole blood.

Prescription Use **XXX** AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

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